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| APPLICATION NO.                        | FILING DATE                       | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-----------------------------------|----------------------|---------------------|------------------|
| 10/553,430                             | 12/26/2006                        | Christopher Hug      | SER-100X            | 3770             |
|  | 7590 02/23/200<br>K LLOYD & SALIW | EXAMINER             |                     |                  |
| A PROFESSIONAL ASSOCIATION             |                                   |                      | DUTT, ADITI         |                  |
| PO Box 142950<br>GAINESVILLE, FL 32614 |                                   |                      | ART UNIT            | PAPER NUMBER     |
|  |                                   |                      | 1649                |                  |
|  |                                   |                      |                     |                  |
|  |                                   |                      | MAIL DATE           | DELIVERY MODE    |
|  |                                   |                      | 02/23/2009          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|   | Application No.   | Applicant(s)  |  |  |  |  |
|---|---|---|--|--|--|--|
|   | 10/553,430  | HUG ET AL.  |  |  |  |  |
| Office Action Summary   | Examiner  | Art Unit  |  |  |  |  |
|   | Aditi Dutt  | 1649  |  |  |  |  |
| The MAILING DATE of this communication app<br>Period for Reply  | ears on the cover sheet with the c  | orrespondence address   |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).  | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim vill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | lely filed the mailing date of this communication. (35 U.S.C. § 133). |  |  |  |  |
| Status  |   |   |  |  |  |  |
| Responsive to communication(s) filed on <u>23 Ja</u> This action is <b>FINAL</b> . 2b)⊠ This     Since this application is in condition for allowar closed in accordance with the practice under E  | action is non-final.<br>nce except for formal matters, pro  |   |  |  |  |  |
| Disposition of Claims   |   |   |  |  |  |  |
| 4) ☐ Claim(s) 59-70 is/are pending in the application 4a) Of the above claim(s) 63-65 is/are withdraw 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 59-62 and 66-70 is/are rejected. 7) ☐ Claim(s) 70 is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or Application Papers 9) ☐ The specification is objected to by the Examine 10) ☐ The drawing(s) filed on 18 October 2005 is/are: Applicant may not request that any objection to the or  | n from consideration. relection requirement. r. a) accepted or b) objected  | •   |  |  |  |  |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  |   |   |  |  |  |  |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.  |   |   |  |  |  |  |
| Priority under 35 U.S.C. § 119  |   |   |  |  |  |  |
| <ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul> |   |   |  |  |  |  |
| Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date 12/26/06.  | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:  | ite   |  |  |  |  |

#### **DETAILED ACTION**

## Status of Application, Amendments and/or Claims

 The amendment of 23 January 2009 in the claims has been entered in full. Claims 1-58 are cancelled. New claims 66-70 are added.

#### Election without traverse

- 2. Applicant's election without traverse of Group V, claims 59-64, in the reply filed on 23 January 2009 is acknowledged.
- 3. Claims 63-65 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 23 January 2009.
- 4. Claims 59-62, and 66-70 drawn to a method of treating a disorder comprising administration of a composition comprising a T-cadherin agonist modulator to an individual, are being considered for examination in the instant application.
- Applicant's election of metabolic disorders, obesity and soluble form of T-cadherin as the species will be considered for examination in the instant application.

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### **Drawings**

6. Figure 2 (1-9) is not labeled. Appropriate correction is required.

### Specification

7. The disclosure is objected to because of the following informalities:

Brief Description of the Drawings

Brief description for Figure 2 corresponding to "Box" numbers 1-9 is missing.

Appropriate correction is required.

Page 18, lines 31 and 32 are identical (i.e. 'a)' is the same as 'b)').

Appropriate correction is required.

# Claim Objections

8. Claims 68 and 70 are objected to because of the following informalities:

Claims 68 and 70 recite the acronym "GPI". The acronym should be spelled out for clarity.

Claim 70 is redundant because it recites the same limitations as claim 68.

Appropriate correction is required.

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### Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- 9. Claims 68 and 70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim fails to identify the metes and bounds of the related subject matter and how that could be ascertained in the stated invention.
- 10. Claims 68 and 70 are rejected under 35 U.S.C. 112, second paragraph, as being vague and unclear, because of the limitation "comprises SEQ ID NO: 1, wherein the GPI-anchor site has been mutated". It is not discernible whether:
  - (i) SEQ ID NO: 1 itself corresponds to the sequence comprising the mutated GPI anchor site, OR
  - (ii) a mutation in the GPI-anchor site results in a change in the SEQ ID NO: 1.

Appropriate clarification is required.

### Claim Rejections - 35 USC § 112-Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 59-62, 66-70 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a metabolic disorder such as obesity by administration of a composition comprising a modulator or an agonist of T-cadherin polypeptide to an individual having such disorder, wherein the T-cadherin polypeptide is a full-length polypeptide that has the glycosylphosphatidylinositol (GPI) anchor domain, does not reasonably provide enablement for a method of treating the said disorders by administering a soluble T-cadherin polypeptide, wherein T-cadherin has the GPI site mutated, or biologically active fragments of T-cadherin polypeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. It is noted that T-cadherin polypeptide is defined in the instant specification as "full-length T-cadherin proteins and to biologically fragments thereof" (page 10, lines 17-19). Also, the sequences referred to a T-cadherin polypeptide indicate the presence of the GPI anchor site, i.e. amino acid 693 (page 10, last para).

12. The claims are directed to a method for treating a metabolic disorder such as obesity comprising administering to an individual in need thereof, a modulator of a T-cadherin polypeptide, wherein the modulator is an agonist, and wherein the modulator is used in combination with a known drug for the treatment of said disorder or obesity. The claims further recite that the modulator is a soluble T-cadherin (i) consisting of amino acids 23 to 692 of SEQ ID NO: 1; (ii) comprising SEQ ID NO: 1, wherein the GPI-anchor site is mutated; and (iii) comprising a heterologous sequence fused to a polypeptide that consists of amino acids 23 to 692 of SEQ ID NO: 1.

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- 13. Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, include the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed. The instant disclosure fails to meet the enablement requirement for the following reasons:
- 14. The specification teaches that T-cadherin, also known as H-cadherin or cadherin 13 belongs to the cell surface protein family of cadherins, however, lacks the transmembrane domain and is attached to cell membrane via a GPI anchor site at the C-terminal region (page 1, lines 20-26). The specification also teaches that T-cadherin is a novel

receptor for the adipose tissue hexameric and high molecular weight (HMW) hormone species, adiponectin or Acrp30 (page 5, lines 29-31; page 8, lines 14-16). Still further, the specification teaches that serum levels of Arcp30 are decreased in obese animal models and in humans (page 6, lines 14-18). Furthermore, using full length T-cadherin, the specification demonstrates the binding studies with the hexameric and HMW species of Arcp30 in mammalian cells (Example 4); and the effect of T-cadherin over-expression on the suppression of Acrp30 induced NF-kB mediated transcription (Example 5, Figure 4). The instant specification defines the "soluble form of T-cadherin" as T-cadherin polypeptide or its fragment not attached to the membrane, wherein the GPI-anchor site is mutated or absent (page 18, lines 24-32; page 19, lines 1-12). However, the instant specification fails to provide any guidance or sound scientific reasoning that would translate the above information to a method using modulators comprising a soluble T-cadherin that have the GPI anchor site mutated or missing. Based on the inadequacy of the information and lack of working examples to indicate that the mutated or soluble T-cadherin will be a reliable modulator for treating obesity and other metabolic disorders, undue experimentation would be required of the skilled artisan to derive at the expected results.

15. Relevant art teaches that T-cadherin or truncated cadherin is a calcium dependent glycoprotein, lacks the transmembrane and cytosolic domains of the common cadherin molecules, and is bound to the plasma

membrane via a GPI anchor site. The art also teaches that T-cadherin is expressed in brain, along with high levels in the skeletal muscle, heart, kidney and aortic tissues (Niermann et al. Biochem Biophys Res Commun 276: 1240-1247, 2000; abstract, Introduction; Hug et al. PNAS 101: 10308-10313, 2004; page 10312, col 2, para 4). The art further teaches that both mature T-cadherin (105 kDa) and its precursor (130kDa) bind to lipoproteins (Tkachuk et al. FEBS Lett 421: 208-212, 1998; abstract, page 210, col 2, para 4) via the GPI moiety (Niermann et al. page 1245, col 1, para 1-2). Niermann et al. further demonstrate that only membrane bound T-cadherin bind lipoproteins in mammalian cells, while T-cadherin cleaved from the cell surface by GPI specific phospholipase, or T-cadherin lacking the GPI signal sequence expressed in the mammalian HEK293 cells do not bind to the lipoproteins (abstract). Thus based upon available information in the related art, a skilled artisan would believe that the GPI anchor site is an important domain in the T-cadherin molecule that could serve as a signaling receptor for the low density lipoproteins as stated by Kipmen-Korgun et al. (J Cardio Pharm 45:418-430, 2005; abstract). Because of the importance of the GPI moiety and because neither the instant specification nor the relevant literature teach that a soluble Tcadherin with a mutated GPI or absence of GPI can be used for the treatment of obesity or any metabolic disorder, the skilled artisan will be subjected to undue experimentation.

16. Furthermore, the instant specification is not enabled for a method of treating obesity by administering a modulator of any fragment, variant or mutant of T-cadherin polypeptide, as broadly defined in the instant specification (pages 10, 11). The problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. While it is known that many amino acid substitutions are generally possible in any given protein the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These or other regions may also be critical determinants of antigenicity. These regions can tolerate only relatively conservative substitutions or no substitutions (see Wells, 1990, Biochemistry 29:8509-8517; Ngo et al., 1994, The Protein Folding Problem and Tertiary Structure Prediction, pp. 492-495). However, Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the protein which are tolerant to change (e.g. such as by amino acid substitutions or deletions), and the nature and extent of changes that can be made in these positions. Even if an active

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or binding site were identified in the specification, they may not be sufficient, as the ordinary artisan would immediately recognize that an active or binding site must assume the proper three-dimensional configuration to be active, which conformation is dependent upon surrounding residues; therefore substitution of non-essential residues can often destroy activity. The art recognizes that function cannot be predicted from structure alone (Bork, 2000, Genome Research 10:398-400; Skolnick et al., 2000, Trends in Biotech. 18(1):34-39, especially p. 36 at Box 2; Doerks et al., 1998, Trends in Genetics 14:248-250; Smith et al., 1997, Nature Biotechnology 15:1222-1223; Brenner, 1999, Trends in Genetics 15:132-133; Bork et al., 1996, Trends in Genetics 12:425-427).

17. Due to the large quantity of experimentation necessary to treat metabolic disorders such as obesity by administering a modulator of any fragment, variant or mutein of T-cadherin polypeptide, or a soluble form of T-cadherin polypeptide lacking GPI anchor site; the lack of direction/guidance presented in the specification regarding the same; the complex nature of the invention; the unpredictability of a desirable therapeutic effect of all molecules of T-cadherin polypeptide on obesity or any metabolic disorder - undue experimentation would be required of the skilled artisan to make and/or use the claimed invention.

Claim Rejections - 35 USC § 112-Written Description

- 18. Claims 59-62, 66-70 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.
- 19. The claims are directed to a method for treating a metabolic disorder such as obesity comprising administering to an individual in need thereof, a modulator of a T-cadherin polypeptide, wherein the modulator is an agonist, and wherein the modulator is used in combination with a known drug for the treatment of the said disorder or obesity. The claims further recite that the modulator is a soluble T-cadherin (i) consisting of amino acids 23 to 692 of SEQ ID NO: 1; (ii) comprising SEQ ID NO: 1, wherein the GPI-anchor site is mutated; and (iii) comprising a heterologous sequence fused to a polypeptide that consists of amino acids 23 to 692 of SEQ ID NO: 1.
- 20. The specification teaches that T-cadherin, also known as H-cadherin or cadherin 13 belongs to the cell surface protein family of cadherins, however, lacks the transmembrane domain and is attached to cell membrane via a GPI anchor site at the C-terminal region (page 1, lines 20-26). The specification also teaches that T-cadherin is a novel receptor for the adipose tissue hexameric and high molecular weight (HMW) hormone species, adiponectin or Acrp30 (page 5, lines 29-31;

page 8, lines 14-16). Still further the specification teaches that serum levels of Arcp30 are decreased in obese animal models and in humans (page 6, lines 14-18). Furthermore, using full length T-cadherin, the specification demonstrates the binding studies with the hexameric and HMW species of Arcp30 in mammalian cells (Example 4); and the effect of T-cadherin over-expression on the suppression of Acrp30 induced NF-kB mediated transcription (Example 5, Figure 4). The instant specification defines the "soluble form of T-cadherin" as T-cadherin polypeptide or its fragment not attached to the membrane, wherein the GPI-anchor site is mutated or absent (page 18, lines 24-32; page 19, lines 1-12).

21. To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of compete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. The specification has not shown a relationship between the structure, function, or properties of the claimed genus of polypeptides and mutant polypeptides. There is not even identification of any particular portion of the T-cadherin polypeptide structure or function that must be conserved, for the claimed function. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed

genus. The brief description in the specification of one full-length T-cadherin peptide (SEQ ID NO: 1), that is biologically active in the treatment of obesity, is not adequate written description of an entire genus of functionally equivalent polypeptides, which incorporate all variants, fragments and mutants for the treatment of a genus of metabolic disorders.

- 22. Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed" (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See Vas-Cath at page 1116).
- 23. With the exception of full-length T-cadherin polypeptide for the treatment of obesity, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation or production. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The *polypeptide itself* is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

- 24. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class.
- 25. Therefore, only full length T-cadherin polypeptide and obesity, but not the full breadth of the claims meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

#### Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

26. The changes made to 35 U.S.C. 102(e) by the American Inventors

Protection Act of 1999 (AIPA) and the Intellectual Property and High

Technology Technical Amendments Act of 2002 do not apply when the

reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

- 27. Claims 59, 60 and 62 are rejected under 35 U.S.C. 102(e) as clearly anticipated by Saudan et al. (International Patent Application publication No. WO 2004/096272 A2, dated 11 November 2004, with a prior filing date of 29 April 2003, application no. 60/466050).
- 28. The claims are directed to a method for treating a metabolic disorder such as obesity comprising administering to an individual in need thereof, a modulator of a T-cadherin polypeptide, wherein the modulator is an agonist, for the treatment of the said disorder or obesity.
- 29. Saudan et al teach molecules and agents interacting with Tcadherin that can mimic the activity of adiponectin. The reference further
  teaches that T-cadherin is a receptor for adiponectin, and agents
  mimicking the action of adiponectin can be administered to patients for the
  treatment of metabolic conditions like obesity (page 6, para 1-2; page 9,
  para 4). Additionally, Saudan et al. teach providing T-cadherin as a
  medicament for treating obesity or metabolic disorders (page 33, para 2).
  It is noted that based on the definition of "agonist" in the instant
  specification which states that the agonist refers to a compound that has
  an effect in the same direction as adiponectin or Arcp30 on T-cadherin,

Saudan et al. teach the method of treating obesity using an agonist of T-cadherin polypeptide. Therefore, Saudan et al. anticipate the invention.

# Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 30. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a). prophylactic
- 31. Claims 59 and 61, are rejected under 35 U.S.C. 103(a) as being unpatentable over Saudan et al. (International Patent Application publication No. WO 2004/096272 A2, dated 11 November 2004, with a prior filing date of 29 April 2003, application no. 60/466050) in view of Weigle (J Clin Endo Metab 88: 2462-2469, 2003).

- 32. The claims are directed to a method for treating a metabolic disorder such as obesity comprising administering to an individual in need thereof, a modulator of a T-cadherin polypeptide, wherein the modulator is used in combination with a known drug for the treatment of the said disorder or obesity.
- 33. The teachings of Saudan et al. are set forth above.
- 34. Saudan et al. do not teach the treatment of obesity using a combination of the T-cadherin modulator in combination with a known drug for the same condition.
- 35. Weigle teach the treatment of obese adult subjects with orlistat, the only approved inhibitor of the gastrointestinal lipases that can reduce the absorption of dietary fat by upto 30% and thereby result in weight loss (page 2464, col 1, para 2, Figure 4).
- 36. Weigle does not use a combination therapy with the modulator of T-cadherin polypeptide.
- 37. Neither Saudan et al. nor Weigle teach a method of treating obesity by administering a combination of a modulator of T-cadherin and orlistat (or any other known drug for obesity). However, in the absence of unexpected results, it would have been <a href="mailto:prima\_facie">prima\_facie</a> obvious to one of ordinary skill in the art to combine the teachings of the references and to treat subjects with a combination of the modulator of T-cadherin polypeptide and orlistat for reducing obesity. Each of these molecules had been taught by the prior art to express treatment for obesity or inducing

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weight loss. The instant situation is amenable to the type of analysis set forth in *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980) wherein the court held that it is <u>prima</u> facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose in order to for a third composition that is to be used for the very same purpose since the idea of combining them flows logically from their having been individually taught in the prior art. Applying the same logic to the instant process claims, given the teaching of the prior art of processes using modulating agents of T-cadherin or orlistat individually as therapeutics for the treatment of obesity, it would have been obvious to treat the said subject with both modulator of T-cadherin and orlistat because the idea of doing so would have logically followed from their having been individually taught in the prior art to be useful as agents for the same purpose of treating obesity. One of ordinary skill in the art would have reasonably expected to treat obesity by administering either the T-cadherin modulator or orlistat or both of these molecules, since both had been demonstrated in the prior art to treat obesity.

38. Thus, the claimed invention as a whole was *prima facie* obvious over the combined teachings of the prior art.

#### Conclusion

39. No claims are allowed.

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40. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is (571) 272-9037. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 5:00 p.m.

- 41. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
- 42. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov/">http://pair-direct.uspto.gov/</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AD 12 February 2009

/Jeffrey Stucker/ Supervisory Patent Examiner, Art Unit 1649